ISSN: 2831-3887

Research Article

Journal of Veterinary Health Science

A Four-Year Survey of Error Reports In A Radiotherapy Department

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Submitted: 29 Sep 2022; **Accepted:** 18 Oct 2022; **Published:** 07 Jan 2023

Citation: Esmati E, Hasoomi N*, Khodadadi A, Andish NM, Ghalehtak R, Kazemian A. (2023). A Four-Year Survey of Error Reports in a Radiotherapy Department. *J Vet Heal Sci*, 4(1), 01-10.

Abstract

Purpose

Patient safety is a fundamental concept in radiotherapy due to the delivery of large radiation doses in a single fraction. Radiotherapy is a highly complex procedure with many steps, which confers a high risk of errors. This study aimed to investigate radiotherapy errors and their effects on patients to provide a framework for increasing our knowledge of radiotherapy, quality of treatment and patient safety.

Materials and Methods

The total number of error reports was 648 during four years of this survey (2017-2020), 51% of which were attributed to near-misses, and the patients were not affected by the errors. Also, 40% of the errors were incident errors, while the rest were non-conformity errors. Meanwhile, the number of treatment courses was 12,755, 32,118, 34,052, and 39,784 throughout the survey during 2017-2020, respectively.

Results

The annual error ratio was 2.2 in 100 treatment courses. Use of a collaborative interprofessional approach led to a decrease in the incident errors by 20% and an increase in near-misses by 24% during the survey (P=.002).

Conclusion

Our outcomes indicated that analyzing radiotherapy errors and their effects on patients can help radiotherapy teams, including radiation oncologists, physicists, and radiation therapists, to provide the best services for the patients; it also improves teamwork and increases the quality of treatment.

Key words: Radiotherapy Errors, Incident Errors, Near-Miss Errors, Patient Safety

Introduction

Radiotherapy is an essential component of cancer treatment. About 50% of cancer patients require radiotherapy for their treatment [1]. Radiotherapy is a highly complex procedure with many steps, which confers a high risk of errors. Although the application of more novel techniques can reduce errors in radiotherapy, it can also be a new source of errors [2, 3].

Patient safety is a fundamental concept in radiotherapy due to the delivery of large radiation doses in a single fraction. The Patient Safety Organization (PSO) has provided a web-based system for radiation oncology specialists, who contribute to the system by recording near-misses and incident errors; this system has been supported by the American Society for Radiation Oncology (ASTRO) website [4]. Since some incident errors have serious adverse effects on the human body, it is important to educate the staff about error reporting to prevent them. In this regard, a book, entitled "Toward Safer Radiotherapy" (TSRT), was published by the National Patient Safety Agency in 2008, providing practical recommendations to reduce errors and increase treatment safety [5]. In radiotherapy, we can define different categories of errors, such as random and systematic errors. Random errors can originate from repeated measurements under similar conditions. They are defined as a standard deviation (SD) in statistical considerations, poor measurement processes, deviations in recording a parameter, or incorrect procedures, whereas systematic errors involve missing the target volume [6]. Random errors influence systematic errors, which are caused by slight variations in patient positioning in different sessions.

Systematic and random error types that should be prevented and reduced can affect the side effects of tumor control by 10%; therefore, it is important to reduce errors and uncertainties to less than 5% [7]. It should be noted that near misses are discovered immediately before treatment delivery and can lead to incident errors if not detected; this type of error is very important, as it represents the protocols of a radiotherapy Center. In organizations with well-trained staff for recording and reporting radiotherapy incidents, it is essential to understand subsequent errors before any unwanted exposure. This is dependent on the performance of quality control teams and their collaboration with other groups working in radiotherapy centers. Generally, incident errors may occur during conventional treatments or even modern therapies, such as stereotactic body radiotherapy (SBRT), intensity-modulated radiation therapy (IMRT), and volumetric modulated arc therapy (VMAT).

The most important part of radiation is providing reproducibility of the treatment site using different immobilization devices and positioning techniques. The aim of radiotherapy is to deliver radiation only to the tumor area and avoid exposing other at-risk organs to radiation. . Complex and rapid technological advances may be associated with errors. To exemplify, a study indicated that Record and Verify (R&V) systems, were responsible for 23% of errors [3]. In another study, use of new technologies and manual beam modifiers was considered as a source of error [8].

Recent studies indicate there is a significant improvements in the error reports through implementing the incident learning system in radiotherapy departmental structure [9, 10]. Marta Bogusz-Czerniewicz, in his study, indicated that incident errors categorized in threes aspects: including organizational standards, physics and technical standards and clinical standards [11]. Several researchers have shown that 35-50% of radiotherapy errors are related to beam modifiers [3, 12, 13]. However, image-guided radiation therapy (IGRT) can correct setup errors in real time for each fraction by using two orthogonal radiography films for matching bony landmarks and a rotational scan for soft tissues, which prevent two types of setup errors, that is, interfraction and intrafraction setup errors [14-16]. In this regard, Matthew et al. developed a near-miss risk index, which scores events on a scale of 0 to 4 (none, mild, moderate, severe, and critical) [17]. The analysis of 2056 incident errors over five years revealed that only 1.95% of them had an impact on the patients, which indicates a substantial decline in the rate of actual and major incidents [18].

Overall, the investigation of errors helps radiotherapy departments to pay more attention to potential errors and avoid systematic and random ones; besides, it can provide different quality assurance protocols [12]. Bogusz-Czerniewicz noted that clear mechanism to monitor and address failure are valuable if they will be implemented, reviewed, audited and improved in place [11].

Incident learning systems can help different organizations to increase patient safety and decrease serious adverse events over time [18-21]. While the majority of radiotherapy error reports are based on reproducibility and setup variations [3, 13, 22-26]. In the present study, we aimed to analyze different types of errors in different stages of radiotherapy, including computed tomographic (CT) simulation, planning, and treatment, and to introduce methods that can reduce them.

Methods and Materials

This study was conducted in a teaching radiation oncology department affiliated to Tehran University of Medical Sciences with four types of conventional and modern linear accelerators. The duration of this survey was four years (2017, 2018, 2019, and 2020). Our radiotherapy center performs two-dimensional (2D) conventional radiotherapy, three-dimensional (3D) conformal radiotherapy (CRT), and IMRT techniques, based on the individualized protocol (flowchart 1). In our center, 2D conventional radiation therapy accounts for less than 10% of all treatments since 2015, and most techniques are based on 3D CRT and recently IMRT. In our radiotherapy department, 30 radiation therapists, 10 radiation oncologists, and 15 physicists, treat 200 patients on a daily basis, using 4 conventional and modern accelerators, including Elekta Company (Compact & Synergy), and Varian Company (C linac 2100C). Two-thousand patients are treated, and 29,237 treatment courses were delivered annually in this center on average.

Patients, treated exclusively by brachytherapy, were excluded from our analysis. At least 15 parameters (e.g., field dimensions, gantry, couch, and collimator angles, MU, and wedges and etc.) were used for each field. Overall, Elekta accelerators (6-10 MV) treated 43% of selected patients for radiotherapy who suffer from breast cancer and 11% of selected patients for radiotherapy who suffer from head and neck cancer. In addition, 5% of them struggled with mediastinal tumors, 14% with pelvic tumors, and 5% with abdominal tumors were treated using the 18-MV Varian or Synergy accelerator. A special paper-based error report [27] was modified and introduced to volunteer radiotherapy team members, mainly radiation therapists (RTT). This is because RTTs are the last line of treatment procedures and they have the ability to detect errors before the first session of treatment based on the quality control checklist, which is attached to treatment document (Near miss errors), and also they have the responsibility to report their incident errors during the treatment fractions. In our center radiation therapist are responsible for CT Simulation and treatment delivery. They also are responsible for quality assurance of the geometry parameters verification in the document file. Every document of each patients will be verified by a QA member (radiation therapist) in the aspect of the conformity of tumor pathology with the treatment area and geometry of plan and recording parameters on the document. To provide a certain protocol for QA, different potential errors were defined in this checklist, which will be mainly checked by radiation therapist. This checklist depicts important factors of the radiotherapy procedures in our oncology department, including visits by radiation oncologists, treatment indications, CT simulation or simulation based on the treatment technique, treatment planning, and treatment delivery (Flowchart 1).

Any event, whether it affected the patients or not, was recorded and confirmed for addressing the system shortcomings. Different causes of errors, including external shielding and wedges as separate sources of errors associated with manual placement, pathology, geometric parameters, and setup variations, were analyzed. Each incident recorded in a paper separately. Treatment sites, including the head, neck, breasts, pelvis, and extremities, were also investigated in this survey.

In this study, errors were analyzed using four classifications. The first classification divided errors into random and systematic, while in the second categorization, the errors were analyzed at five levels (level 1-3: incident errors; level 4: near-misses; and level 5: non-conformity errors), according to the TSRT book (Figure 4) [5]. In the third categorization, errors were divided based on the cause (Table 1). In the fourth categorization, the percentage of treatment area associated with recording errors indicate 43 % of the patients are breast cancers which covers 23% of error reports(Figure 5 & Figure 6). Finally, the root causes of errors were analyzed using the fishbone diagram procedure (Figure 7). The collected data were analyzed using Statistical Package for the Social Sciences (SPSS) for Windows Version 16 (SPSS Inc; Chicago, IL, USA). In all analytical tests, $P < 0.05$ was considered as statistically significant. We used Chi-Square test of independence to determine if there is a significant relationship between two nominal (categorical) variables and ANOVA test for significant relationship of continuous variables.

Table 1: Incident Records in Different Years of the Survey Based On the Root Causes

ERRORS	First Year	Second Year	third Year	Forth Year
Pathology and treatment Area	6	4	10	1
Incorrect Geometry Parameters& BEV)	29	26	38	57
total dose, dose/fraction	30	25	20	28
Address	17	6	15	10
Radiosensitizer	3	2	3	0
Bolus	21	15	7	7
Set Up	22	20	37	15
Shield design	1	3	13	3
Attenuation Factor(Couch & Shield)	15	6	5	8
Treatment Planning	11	6	7	8
Immobilization & Fixation	2	4	6	2
Tattoo	3	2	0	3
others	5	0	8	5

Results

The total number of error reports was 648 during four years of this survey, 51% of which were near misses, 40% were incident errors, and the rest were non-conformity errors throughout the survey. For instance, in the third year of the survey, 170 error reports (49% incident errors, 44% near misses, and 7% non-conformity errors) were documented, and error ratio (the number of error reports per new patient) was 10%.

Figure 1 indicates graph of error ratio in the 4 years. In the first, second, third and fourth years of the survey, a total of 162, 116, 170 and 200 error reports per 2185, and 1467, 1555 and 1724 new patients were recorded. Meanwhile, the number of treatment courses was 12,755, 32,118, 34,052, and 39,784, respectively. The analysis of data indicated a statistically significant difference (P<.001) in the increased rate of errors during the survey. As shown in Table 1, the number of reports has been somewhat stabilized, and we have made progress by reducing some of the error causes during the survey, such as treatment planning, attenuation factor calculation, bolus calculation, dose/fraction, setup design, and shield design by 3%(P=.001), 7%(P<.001), 14% (P<.001), 2% P=(.001), 7% (P=.007), and 10%(P<.001) respectively, while other causes, such as geometric parameters, increased by 28%(P<..001).

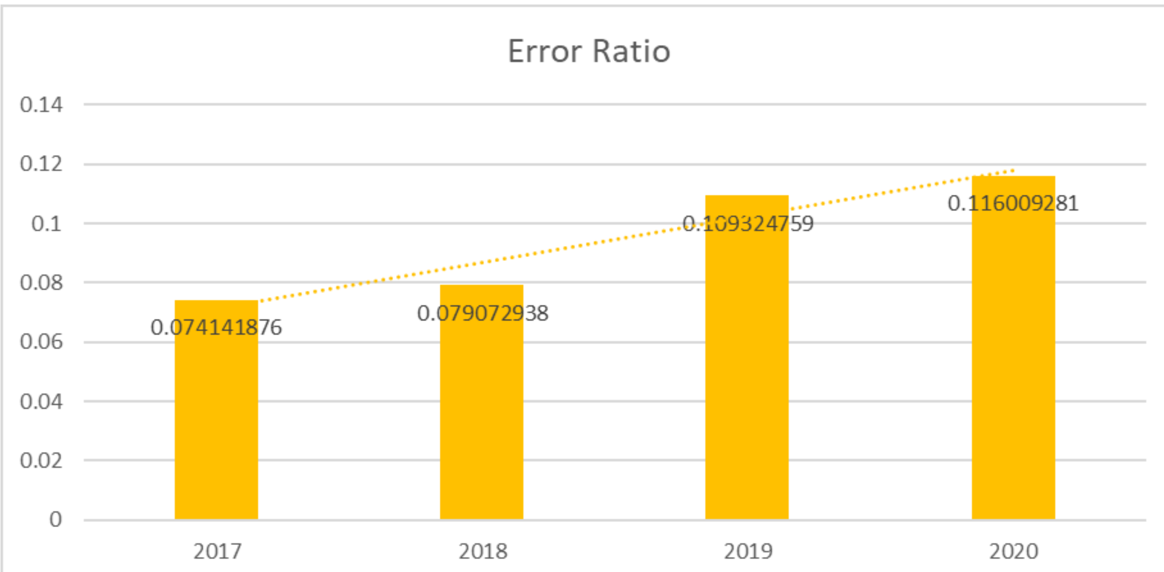

Figure 1: Error Ratio: Error Report Rates in Different Years of Survey

Table 2: Error Causes Types

Geometry parameter Errors	Treatment Planning Errors	Set up Errors
wedge angle	OAR in the treatment field	overlapping of fields
Shielding	Isocenter Depth	geometry parameters (, gantry collimator, MU)
Asymmetric and Symmetric fields	Overlapping of adjacent fields	incorrect addressing
Gantry, Couch, collimator angle	unwanted gap between fields	treatment extra fraction
SSD	improper inferior border of breast field	SSD, Isocenter, VRT
MU	Addressing	incorrect Isocenter
Bolus	CT of contralateral breast	treatment of thorax instead of Lumbar
couch Factor	addressing from far marker	bolus
Attenuation factor of Perspex and Couch	Medication such as Xeloda	positioning
incorrect treatment phase	laser shifting	thermoplastic shrinkage /contraction

Figure 2 represent categorical variables of error level in the survey. The most significant number of error reports relates to level 4. As figure 2 illustrates level 4 errors increased significantly in the year 2020. level 1 errors had the lowest frequency which refer to the incident errors that means the dose delivered to the patient was more than 20% of the prescribed dose (Figure 2). For example, an organ of a metastatic patient was treated incorrectly for eight fractions. According to Figure 3, the number of incident errors was 72, 49, 84, and 52 respectively during 2017-2020. Also, 88, 61, 75, and 112 near-misses were recorded from 2017 to 2020, respectively.

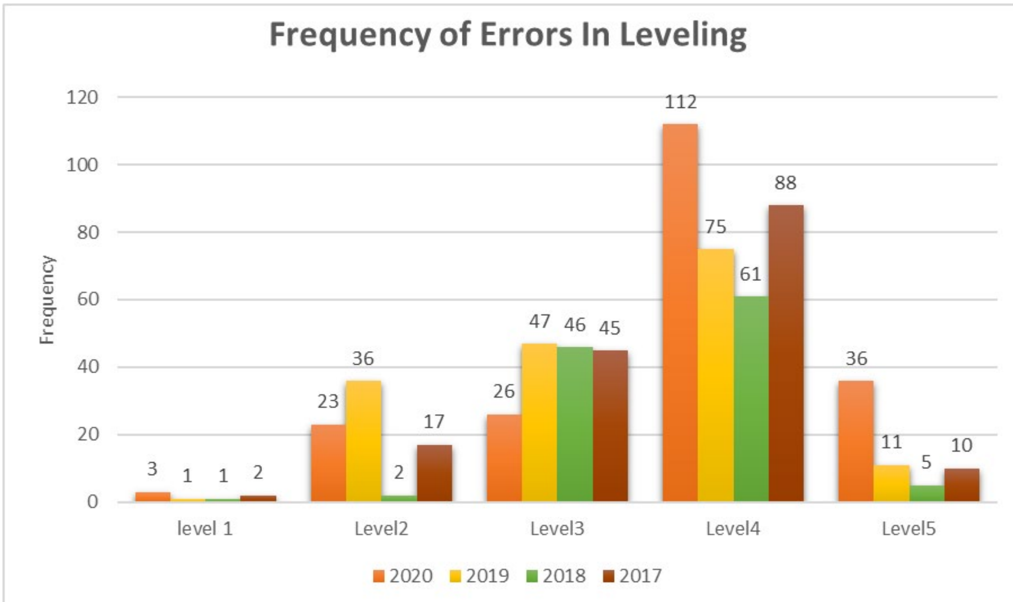

Figure 2: Frequency of errors in leveling: Frequency of errors based on the 5 levels described in the book Toward Safer Radiotherapy

Some errors were associated with infrastructure factors, and procedures for the final treatment delivery were sometimes unchecked or unverified. Overall, 78.24% of errors were systematic, and 21.76% were random. The most common error category was errors in recording geometric parameters (150 reports) followed by setup discrepancies (94 reports),. More details are presented in Table 1. Figure 2 illustrates the frequency of errors based on the error level(1-5) during 2017-2020. It can be seen that level 4 errors (near-misses) had a higher rates among other levels. Figure 3 represents the comparison results of incident errors and near misses. Overall, The near-miss errors increased throughout the survey by 24%. In contrast to incident errors that decreased during the survey by 20% (P=.002).

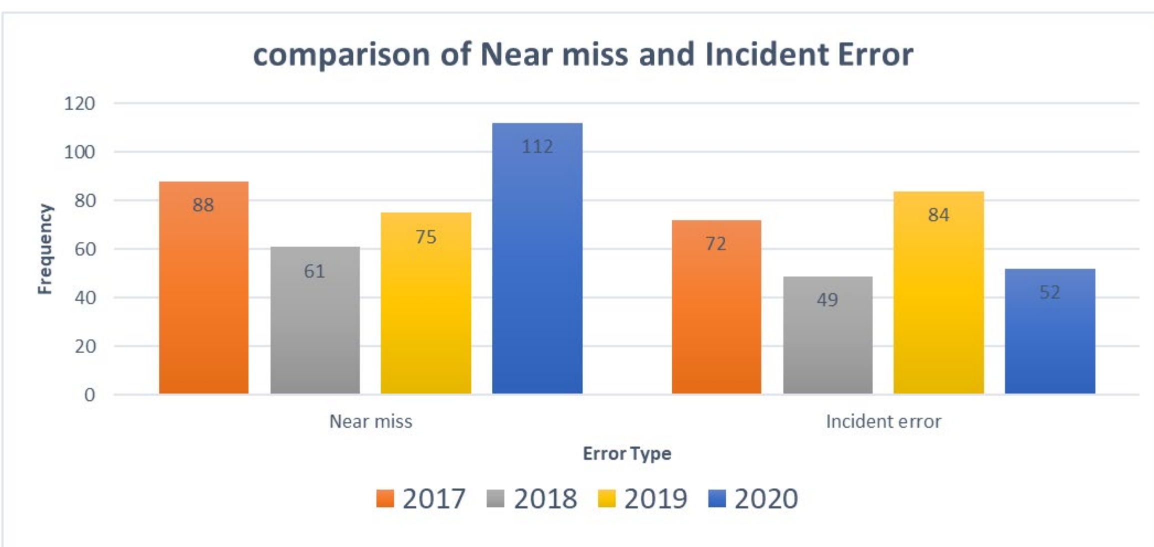

Figure 3: Comparison of Incident error and near Miss Comparison of Incident Error and Near Miss in Different Years of the Survey

As Figure 4 illustrates, the error frequencies can be categorized based on the organs. Head and neck treatment area had the highest share of reports (35%), followed by breast cancer reports(23%). Moreover, percentage of patients that radiotherapy were an indication of their treatment are shown in the figure 5.

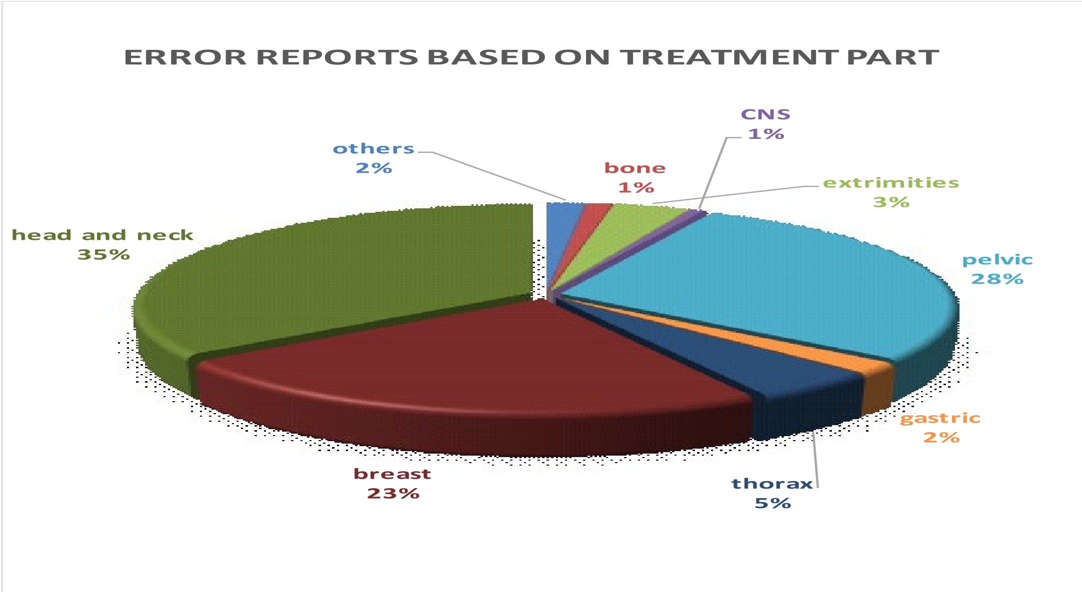

Figure 4: Error Reports Percentages Based On the Treatment Part

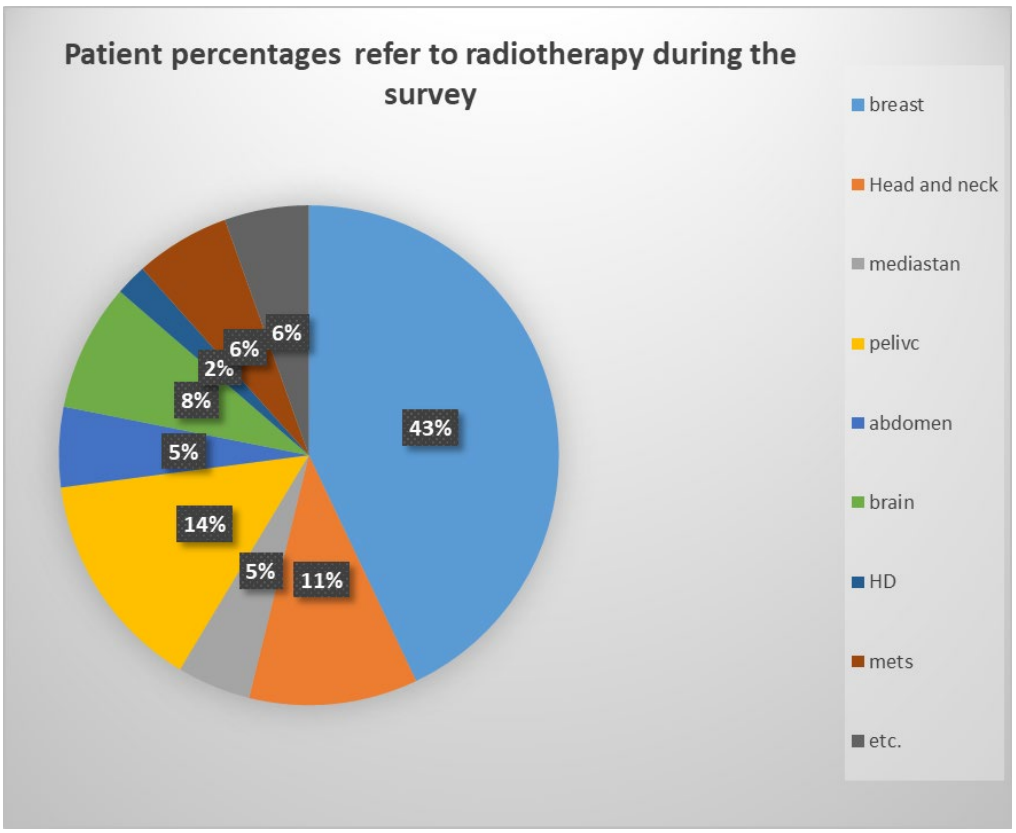

Figure 5: Percentages of Patients Who Suffer From Different Tumors Refer To Radiotherapy in Our Center

In our study, a noteworthy point is that there is a relation between error causes and frequency of different cancers throughout the survey. For example, 49% of patients candidates for radiotherapy treatment suffer from breast cancer, skin malignancies or some type of sarcoma need bolus in their treatment procedures, while 7.7 % of reports were subjected to bolus errors, therefore, the rate of this error is comparatively low(15%). In contrast, 11% of patients candidate for radiotherapy treatment were head and neck, while the total error rate is almost 35%.

Discussion and Conclusion

Incident learning systems, as a strategy for reporting, analyzing, and presenting methods to prevent errors, have played an essential role in different fields, including airline accidents and nuclear power [28, 29]. Evidence suggests that comprehensive screening and error recording and reporting can help reduce random and systematic errors. Almost 78% of errors in this study were systematic and could be avoided using standard flowcharts and precise screening before the treatment procedure or applying R&V systems.

Error reports of head and neck cancer (35%) indicate that we must be more cautious about this type of cancer (Figure 5 & Figure 6). Our center has employed several methods, such as implementation of new technologies and several new treatment techniques to make treatment planning as simple as possible. Besides, monitoring methods (using different planning parameters) and different parallel actions were performed to guarantee the treatment procedure and address the system weaknesses. One of the strategies developed by our multidisciplinary team to address some human errors was the simultaneous checking of the vertical number and source-skin distance (SSD) and verifying that the Beam's eye view (BEV) provided adequate information for radiation therapists to ensure the correct site of treatment. Although R&V systems can reduce many incidents errors, many linear accelerators (LINAC) are still in service, without utilizing R&V systems. A review of the most important finding in our study support Heinrich Accident Triangle theory and Reasons' Swiss cheese model that near misses and incident errors have similar fundamental causes. The present study offer clear evidence that reduction of near misses will lead to the reduction of incident errors. Overall, error incidents cannot be prevented in the medical environment, but they can be reduced by creating a non-punitive environment that can lead to the detection and correction of medical errors [30, 31].

Errors can be analyzed based on the fishbone diagram or "five-why" flowchart (Figure 6). In this regard, Gregory A et al. reported a fishbone structure and identified different types of errors in radiotherapy, most of which could be prevented [2]. Clearly, incident learning systems in radiotherapy departments can help identify the root causes of errors and increase the knowledge of quality assurance teams and staff [17].

In order to screening the treatment procedure before any exposure, level 1 of error occurs at a low frequency in major clinical practices. The role of the quality control team is important in all error levels. In addition, the quality control team can prevent most geometric errors, which may convert to level-3 errors.

Smith showed that the error rate declined over time by 1.3 per 1000 treatment attendances. Our finding imply that the mean annual error ratio was 2.2 in 100 treatment courses, but the error rates had been increased throughout the survey. One possible conclusion is that in some months, the load of patients and new apprentices in the educational department could lead to more recording errors, which indicates the necessity of more strict regulations in periods of higher clinical load and internship [32].

Wright discovered event reporting had been increased in four different sites. Our study carried out in one center and in 4 years, which indicated an increase in event reporting. It could be related to the dedicating cash award for every event reporting [9].

Implication of the study showed that setup errors also are very important; one reason could be that these type of errors attributed to miss the target volume. Therefore, these findings lead us to believe that load of patients and the accelerator capabilities are quite important.

Possible explanation for error roots categorization in fish bone diagram (figure 6) mean that which team should be responsible to manage and prevent potential errors. Systematic errors were primarily caused when the procedure fails to follow standard protocols, as shown by other researchers [33]. Therefore, most errors can be prevented by adhering to protocols and using flowcharts. Generally, the causes of radiotherapy errors are complex, and it is not ethical to consider only one team to be responsible for them.

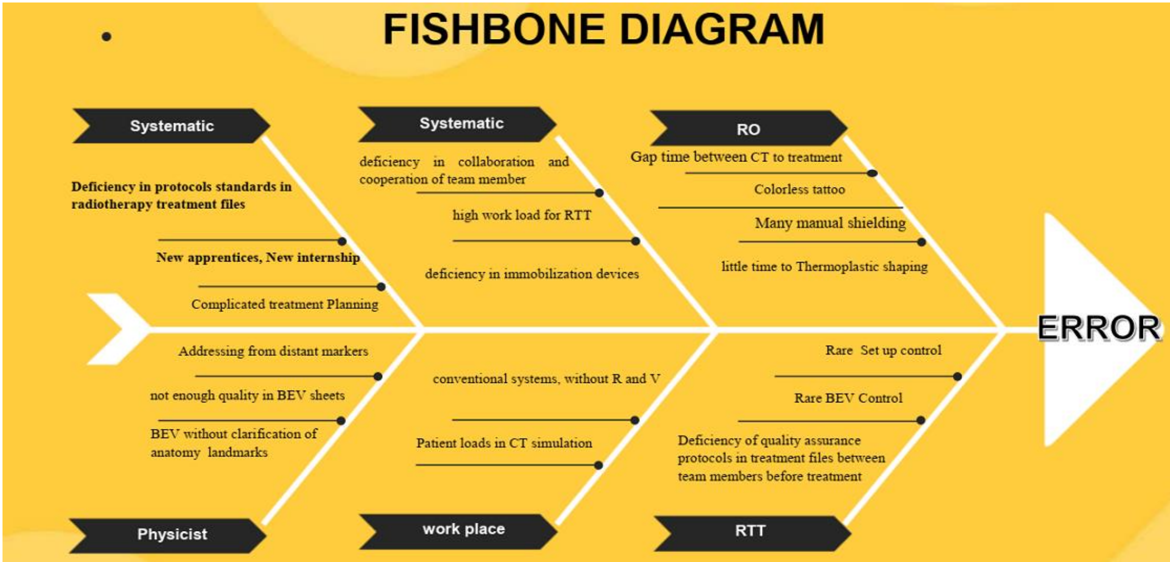

Figure 6: Fish Bone Diagram Analysis of Error Roots via Fishbone Diagram

The Safety in Radiation Oncology (SAFRON) and the Radiation Oncology Safety Information System (ROSIS) are two voluntary web-based radiation oncology incident learning systems, developed by the International Atomic Energy Agency (IAEA) and the European Society for Therapeutic Radiology and Oncology (ESTRO), based on the idea that safety is no accident [34, 35]. In 2011, the ASTRO and the American Association of Physicists in Medicine (AAPM), in collaboration with the Clarity PSO, provided a nationwide incident learning system, called the Radiation Oncology-Incident Learning System (RO-ILS), to share learning experiences with different radiation oncology institutions [36].

Generally, the outcomes of incident learning systems include a significant shift in the attitude of Radiation Therapists (RTTs). This research provide evidence that we have substantial agreement on system improvement by engagement in individual reporting , safety improvement, concerns about punitive actions, and increased confidence that reporting leads to [17]. A survey indicated that a punitive system and strict rules often do not prevent errors and cannot provide pragmatic solutions [37].

In conclusion, although the rate of radiotherapy errors has not changed over time, an active safety culture and voluntary reporting have been promoted by the applied methods. Overall, support by the department authorities can provide opportunities to analyze and address errors and increase the quality of treatments using a collaborative interprofessional approach.

Declarations

Funding

There is no funding

Conflicts of Interest/Competing Interests

There is no conflict of interests

Ethics Approval

Not applicable

Consent to Participate

Not applicable

Consent for Publication

The participants have consented to the submission of this report to the journal

Availability of Data and Material

Derived data supporting the findings of this study are available from the corresponding author on request

Code Availability

Not applicable

Authors' Contributions

Dr. Esmati and Mrs. Hasoomi conceived of the presented idea. Mrs.Hasoomi developed the theory and performed the computations. Dr Ghalehtaki. And Dr. Esmati verified the analytical methods. Mrs Khodadadi encouraged Mrs Hasoomi to investigate this comparison between different years and helped Mrs Hasoomi to accumulate data of this work. Mrs Hasoomi performed the analysis, wrote the manuscript in consultation with Dr Esmati. Mrs Maalandish assist in analyzing data in SPSS. Dr Kazemian provided critical feedback and helped shape the research. All authors discussed the results and contributed to the final manuscript.

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